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Title: Delphi Survey

Description: 27 statements across four sections that appeared in the online Delphi survey

Instructions: Please rate how much you personally agree or disagree with the following statements. Some of the statements are introduced with a scenario. Please read the scenario carefully before rating the relevant statement.

Throughout the survey, please score each statement using the following 9-point Likert scale:

1. Strongly agree
2. Agree
3. Moderately agree
4. Mildly agree
5. Undecided
6. Mildly disagree
7. Moderately disagree
8. Disagree
9. Strongly disagree

Section One: Scenarios			
#	Scenario	Scenario description	Statement (to score using Likert Scale)
1.	Giving a participant too much information about possible harms	John was thinking about enrolling in a trial of a new drug to treat migraines. He read the participant information leaflet very carefully, and in several places the leaflet contained information about gastrointestinal side effects. He didn't know what this meant so he looked it up and figured out that it probably meant stomach aches and nausea. He didn't find much information about the benefits of the new drug, but his doctor said it was worth a try and why would his doctor say that if it wasn't going to help? John enrolled in the trial, and his migraine symptoms got a bit better, but every evening he suffered from stomach aches and withdrew from the trial.	Statement 1: Potential harms that are not very serious do not need to be emphasized.
2.	Not telling a participant about harms enough	Jane had enrolled in a trial of a new 'disease modifying antirheumatic drug' (DMARD) to treat arthritis. The drug seemed to work very well. Then, she read an article in the newspaper about how DMARDs can increase the risk of getting some types of cancer. She asked the trial	Statement 2. Potentially serious harms need to be emphasized, even if they are very rare.

		doctor, who said that the risk of cancer was very low. He then showed her the participant information leaflet she had signed a number of months ago. It listed cancer as a possible side effect only towards the end of the document, using language Jane didn't understand and thought was the 'small print.'	
3.	Comparison with what happens if we take nothing	Marie stopped taking her statin drugs because they caused muscle pain. Her doctor suggested that she should try alternating between taking statins and taking a placebo pill every two weeks for three months. She didn't know whether she was taking the statin or the placebo. At the end of the three months, her doctor showed her that she had as much muscle pain with the placebo as she did with the statin.	Statement 3. Potential benefits and harms of a clinical trial need to be compared with what happens if the participant does not take part in the trial.
4.	Positive framing	Two trials were recruiting people with psoriasis to test new drugs. Andrew had psoriasis and asked about information about both trials. In the information leaflet describing the first trial, the drug was described as having 'common side-effects, affecting 1 in 10 people'. In the second, the side-effects were described as 'uncommon: 90% of people will not be affected.' Andrew felt safer enrolling in the second trial. <i>Saying (1) 'this drug has a common side effect that affects 1 in 10 people' is logically the same thing as saying (2) 'this drug has an uncommon side effect: 90% of people who take it are not affected.' The second way of saying it is called 'positive framing'.</i>	Statement 4. It is okay to use 'positive framing' when describing how severe harms can be.

Section Two: Describing potential benefits of a clinical trial	
#	Statement (to score using Likert Scale)
5.	Benefits are never completely certain, so they should not be described.
6.	Potential benefits should be described more fully than potential harms.
7.	The most likely potential benefits should be described.
8.	Any likely benefits to the participant (including embryos, foetus, nursing infants) should be described.
9.	General potential benefits (such as 'the medicine may help you and your cancer') should

	be described.
10.	Concrete, specific potential benefits (such as ‘this medicine is designed to enable you to walk farther before becoming breathless’) should be described.
11.	Only the most important potential benefits should be described. If too many are included the reader might become confused. A complete list can be contained in an appendix or online.
Section 3: Describing potential harms of a clinical trial	
12.	Participants should not be told about potential harms.
13.	Potential harms should be described more fully than potential trial benefits.
14.	Only the most common possible harms should be mentioned. This will focus the reader’s attention and minimize overload.
15.	The harms should be separated into serious (life threatening, causing permanent damage) and less serious (like a mild headache that goes away quickly).
16.	Not all potential harms are known, especially for new treatments that have not been studied extensively. Participants need to know that not all potential harms can be listed.
17.	Sometimes harms are discovered after the trial begins. As soon as they are discovered, participants need to be told about them.
18.	Risks to conceiving/fathering a child, pregnancy, or breastfeeding should be emphasized.
19.	It’s okay to use ‘positive framing’. That is, it is okay to say ‘this treatment is safe for 90% of the people who take it’ instead of ‘this treatment causes side effects for 10% of the people who take it’.
Section Four: The ordering and placement of benefits and harms in the participant leaflet layout	
20.	Potential harms should be described in pictures as well as words.
21.	Potential trial harms should be described in such a way that they can be compared to what would happen if participant did not take part in the trial.
22.	Potential benefits should be described after harms.
23.	Potential benefits and harms should be beside to each other (for example in two columns).
24.	Information about potential benefits or harms should be presented apart by one or more pages.
25.	Information about potential benefits and harms should be mentioned in more than one place in the leaflet.
26.	A complete (detailed) description of the potential harms (and the likelihood of each harm) should be provided in a table in an appendix.
27.	Drug fact boxes (see below) divide harms into serious and non-serious. This way of presenting harms is helpful.

What difference did ABILIFY make?		Anti-depressant + ABILIFY (10 mg each day)	vs.	Anti-depressant + PLACEBO (No drug)
How did ABILIFY help?				
Depression scores improved by 3 points more than placebo (on a scale from 0 to 60).		9 points better	vs.	6 points better
11% more people had an important response and were no longer considered to have major depression		26%	vs.	15%
Functioning scores improved by 0.5 points more than placebo (on a scale from 0 to 10).		1.2 points better	vs.	0.7 points better
What were ABILIFY'S side effects?				
Serious side effects				
21% more people developed akathisia - severe restlessness that makes it hard to keep still		25%	vs.	4%
3% more people developed movement disorders –like Parkinson's disease		8%	vs.	5%
Symptom side effects				
6% more people had insomnia		8%	vs.	2%
5% more had blurred vision		6%	vs.	1%
4% more had substantial weight gain		5%	vs.	1%
4% more had fatigue		8%	vs.	4%
3% more had constipation		5%	vs.	2%
WARNINGS ABOUT UNCOMMON LIFE-THREATENING AND VERY SERIOUS SIDE EFFECTS				
Young adults using anti-depressants for major depression have a higher risk of suicidal thinking and behavior.				
Elderly patients with dementia-related psychosis should not use antipsychotic drugs – like ABILIFY —because they increase death.				
Antipsychotic drugs cause: Neuroleptic Malignant Syndrome (very high fever and blood pressure, delirium), Tardive Dyskinesia (uncontrollable facial / body movements), Dangerous Heart Rhythms, Seizures, Low White Blood Cells, Trouble Swallowing, Aspiration Pneumonia, Diabetes, Low Blood Pressure, Trouble Regulating Body Temperature				